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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. Ser. No. : 10/644,288  
Inventor : Paul Diamond  
Filing Date : August 20, 2003  
Title : REGULATION OF POLYNUCLEIC ACID  
ACTIVITY AND EXPRESSION  
Examiner : I. Popa  
Group Art Unit : 1633

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| I hereby certify that this paper is being deposited with the United States Postal Service as First Class Mail on <b>January 3, 2006</b> under 37 C.F.R. §1.8 in an envelope addressed to the:<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, VA 22313-1450 |                   |
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| <i>Paul Diamond</i>   | 3 JANUARY 2006    |
| Signature   | Date of Signature |

Commissioner for Patents  
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION AND ELECTION REQUIREMENT**

- 1) This communication is submitted in response to the Office Action mailed December 14, 2005 in the referenced application ("the Office Action") in which a requirement for restriction and election was made.
- 2) Applicant hereby elects the following invention and group, as specified in the December 14, 2005 Office Action, **with traverse**:
  - a) Invention II. corresponding to claims 17-24; and

- b) Group II(iii), corresponding to claim 24.
- 3) Conditional on the withdrawal of the restriction requirement between Inventions II and III requested hereinbelow, Applicant makes the following election of categories for claims currently designated as being within Invention III (see Office Action, page 4, ¶5):
- a) Promoter: group III(ii) corresponding to claims 27 and 32 drawn to a constitutively active promoter; and
- b) Multi-cellular organism: group III(v) corresponding to claim 36, drawn to a transgenic plant.
- 4) Applicant consents to the withdrawal of the claims of Invention I (claims 1-16), but not to the withdrawal of the claims of Invention III (claims 25-36).
- 5) Applicant submits that the restriction requirement asserted between Invention II (claims 17-24) and Invention III (claims 25-36) is not proper and is traversed for the following reasons.
- 6) There are two criteria for proper restriction between inventions, as described in MPEP 803(I.), reprinted below:
- I. CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS
- There are two criteria for a proper requirement for restriction between patentably distinct inventions:
- a) The inventions must be independent (see MPEP § 802.01, § 806.06, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(j)); and
- b) There would be a serious burden on the examiner if restriction is not required (see MPEP § 803.02, § 808, and § 808.02).
- 7) First, as acknowledged on page 2, ¶2 of the Office Action, Inventions II and III (and also Invention I) are all classified within the same class and subclass, namely class 435, subclass 375. Thus, the statement present on page 7, ¶7 of the Office Action that “the inventions are distinct and have acquired a separate status in the art as shown by their different classification” is not correct.

- 8) Second, the Examiner has erred on page 5, paragraph 6 of the Office Action, where it is asserted that “the inventions of groups I-III...are not required for one another and result in different products.” On closer inspection, it will be apparent to the Examiner that the independent claims of Invention I are generic to those of Invention II and the independent claims of Invention II are generic to those of Invention III. The methods of each group share the common inventive element of causing RNA silencing against a transcriptional regulator to affect transcription of a gene regulated by the regulator. Claims II and III are further related by the manner in which a preselected DNA sequence is excised/excisable in response to RNA silencing of a transcriptional regulator. The cell claims of the three groups are similarly related.
- 9) Third, with specific respect to pending Inventions II and III, it is apparent that the method and cell claims of Invention III are a special case of the corresponding generic claims of Invention II. For example, independent method claim 17 of Invention II recites a method for selectively excising a preselected DNA sequence from a cellular genome by causing RNA silencing against the mRNA transcript of a repressor protein. Independent method claim 25 of Invention III shares the same elements as claim 17, but in claim 25 the preselected DNA sequence to be excised is a blocking sequence and the surrounding sequences are a promoter and a preselected gene separated by the blocking sequence. **In short, claim 25 cannot be practiced without practicing claim 17.** In fact, it is clear that claim 25 could have been written as a dependent claim of claim 17. Independent cell claim 18 of Invention II and independent cell claim 29 of Invention III are similarly related.
- 10) Given the clarification, set forth above, of the relationship between designated Inventions II and III and their common classification, it is not seen how an undue burden could be presented by examination of both sets of respective claims. In fact, since the independent claims of Invention II are generic to the independent claims of Invention III, it would be most efficient to examine them together rather than in separate applications. Moreover, the reasons presented herein for withdrawal of the restriction requirement between Inventions II and III should be regarded with even more significance given that Applicant has consented to withdrawal of the broadest set of claims, those of Invention I (claims 1-16).

- 11) In view of the above, Applicant respectfully requests that the requirement for restriction is removed between Inventions II (claims 17-24) and III (claims 25-36). If after carefully considering this paper, the Examiner is still of the opinion that the restriction should remain between Inventions II and III, Applicant respectfully requests a further opportunity to address the issues presented herein in a telephone interview with the Examiner.
- 12) Accordingly, examination and allowance of claims 17-36 is hereby requested.

Date: January 3, 2006

Respectfully submitted,

A handwritten signature in cursive script, reading "Paul Diamond". The signature is written in black ink and is positioned above a horizontal line.

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